RINVOQ® upadacitinib

For moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC) in adult TNFi-IR patients.[1]

IBD DOSING & MONITORING GUIDE

IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

INDICATIONS[1]

RINVOQ is indicated for the treatment of adults with:

- **Moderately to severely active Crohn's disease** who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Moderately to severely active ulcerative colitis** who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biological therapies for Crohn's disease or ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

Malignancies: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information for RINVOQ, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 8.

Please visit rxabbvie.com/pdf/rinvoq_pi.pdf for full Prescribing Information.

Dosing guide for adult TNFi-IR patients with moderately to severely active **Crohn's disease (CD)**

FIRST AND ONLY ONCE-DAILY PILL FOR MODERATE TO SEVERE CD[1,2]

RINVOQ is a once-daily pill that comes in one strength for induction and two strengths for maintenance.[1]

12-WEEK INDUCTION DOSE FOR CROHN'S DISEASE

45 MG

The recommended induction dose of RINVOQ is **45 mg** once daily for 12 weeks.[1]

NDC 0074-1043-28[1]
28 count
Pill not actual size

ADMINISTRATION

Instruct patients to take **1 pill, once daily with or without food**[1]

Advise patients to **avoid food or drink containing grapefruit** during treatment with RINVOQ[1]

Ensure pill is taken whole. Do not split, crush, or chew[1]

MEDICATION RESIDUE IN STOOL

Instruct patients to **notify their healthcare provider** if they repeatedly notice intact RINVOQ **tablet or fragments in stool or ostomy output**.[1]

IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

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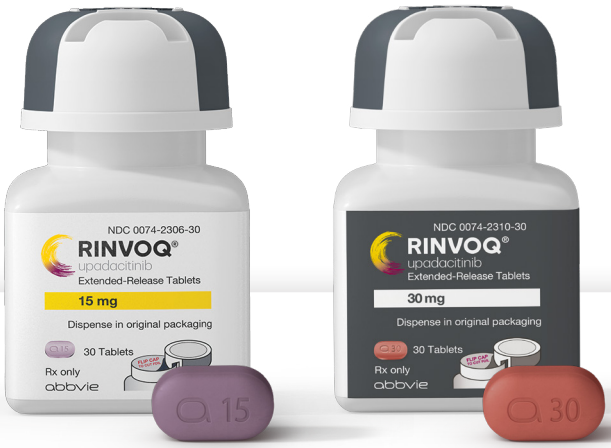
RINVOQ® upadacitinib

Dosing guide for adult TNFi-IR patients with moderately to severely active **Crohn's disease (CD)**

MAINTENANCE DOSE

15 MG OR 30 MG



NDC 0074-2306-30[1]
30 count

NDC 0074-2310-30[1]
30 count

The recommended dose of RINVOQ for maintenance treatment is **15 mg** once daily.[1]

A maintenance dose of **30 mg** once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue RINVOQ if an adequate therapeutic response is not achieved with the 30 mg dose.

Use the lowest effective dosage needed to maintain response.[1]

Pills not actual size

DOSING RECOMMENDATIONS FOR RENAL OR HEPATIC IMPAIRMENT & DRUG INTERACTION

For patients with severe renal impairment (eGFR 15 to <30 mL/min/1.73 m^2), mild or moderate hepatic impairment (Child-Pugh A or B), and for those receiving strong CYP3A4 inhibitors, the recommended dosage is[1]:

- Induction: 30 mg once daily for 12 weeks[1]
- Maintenance: 15 mg once daily[1]

No dosage adjustment is needed for patients with mild or moderate renal impairment (eGFR ≥30 mL/min/1.73m^2).[1]

RINVOQ is not recommended for use in patients with end-stage renal disease (eGFR <15 mL/min/1.73m^2) and in patients with severe hepatic impairment (Child-Pugh C).[1]

eGFR=estimated glomerular filtration rate; IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

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RINVOQ® upadacitinib

Dosing guide for adult TNFi-IR patients with moderately to severely active **ulcerative colitis**

ONE PILL, ONCE DAILY

RINVOQ is a once-daily pill that comes in one strength for induction and two strengths for maintenance.[1]

8-WEEK INDUCTION DOSE FOR ULCERATIVE COLITIS

45 MG

The recommended induction dose of RINVOQ is **45 mg** once daily for 8 weeks.[1]

NDC 0074-1043-28[1]
28 count
Pill not actual size

ADMINISTRATION

Instruct patients to take **1 pill, once daily with or without food**[1]

Advise patients to **avoid food or drink containing grapefruit** during treatment with RINVOQ[1]

Ensure pill is taken whole. Do not split, crush, or chew[1]

MEDICATION RESIDUE IN STOOL

Instruct patients to **notify their healthcare provider** if they repeatedly notice intact RINVOQ **tablet or fragments in stool or ostomy output**.[1]

IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

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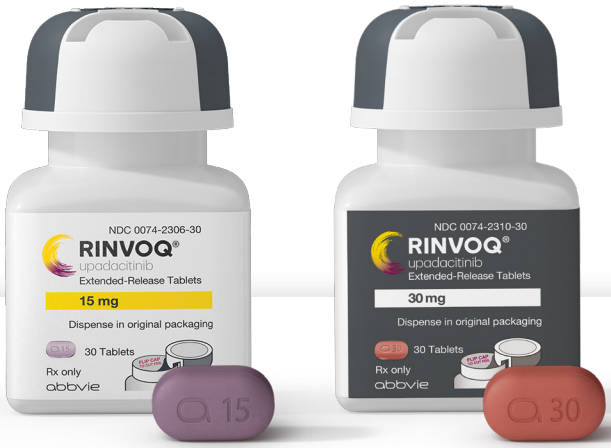
Dosing guide for adult TNFi-IR patients with moderately to severely active **ulcerative colitis**



NDC 0074-2306-30[1]
30 count

NDC 0074-2310-30[1]
30 count

MAINTENANCE DOSE

15 MG OR 30 MG

The recommended dose of RINVOQ for maintenance of UC is **15 mg** once daily.[1]

A dosage of **30 mg** once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue RINVOQ if an adequate therapeutic response is not achieved with the 30 mg dosage.[1]

Use the lowest effective dosage needed to maintain response.[1]

Pills not actual size

DOSING RECOMMENDATIONS FOR RENAL OR HEPATIC IMPAIRMENT & DRUG INTERACTION

For patients with severe renal impairment (eGFR 15 to <30 mL/min/1.73m^2), mild or moderate hepatic impairment (Child-Pugh A or B), and for those receiving strong CYP3A4 inhibitors, the recommended dosage is[1]:

- Induction: 30 mg once daily for 8 weeks[1]
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No dosage adjustment is needed for patients with mild or moderate renal impairment (eGFR ≥30 mL/min/1.73m^2).[1]

RINVOQ is not recommended for use in patients with end-stage renal disease (eGFR <15 mL/min/1.73m^2) and in patients with severe hepatic impairment (Child-Pugh C).[1]

eGFR=estimated glomerular filtration rate; IR=intolerance or inadequate response; TNFi=tumor necrosis factor inhibitor.

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RINVOQ® upadacitinib

LAB MONITORING AND DOSING CONSIDERATIONS

PERFORM LAB TESTING FOR:

	Lab Parameter	Check Lab Values[1]	Treatment should NOT be INITIATED or CONTINUED if[1]
CBC Differential	Neutrophils	At baseline and periodically thereafter according to routine patient management	<1000 cells/mm^3*
	Lymphocytes		<500 cells/mm^3*
	Hemoglobin		<8 g/dL*
	Liver Enzymes		Elevated liver enzymes & suspected drug-induced injury
	Lipids	**At 12 weeks** and thereafter according to clinical guidelines	

INTERRUPT IF PATIENT DEVELOPS A SERIOUS OR OPPORTUNISTIC INFECTION[1]

***Treatment can be initiated or restarted after levels return above specified values, drug-induced liver injury diagnosis is excluded, and infection is controlled.[1]**

SAFETY CONSIDERATIONS[1]

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COMMITTED TO EXCEPTIONAL SUPPORT & ACCESS

>95%

PREFERRED COMMERCIAL & MEDICARE PART D COVERAGE[3§‖]

National Commercial and Medicare Part D Formulary coverage under the pharmacy benefit as of April 2024.[3]

Encourage your patients to enroll in RINVOQ Complete:

One-to-One Support
Nurse Ambassadors* and Access Specialists provide 1:1 support to help navigate insurance.

Affordability
Eligible, commercially insured patients may pay **as little as $0** per month on their prescription and can be reimbursed for out-of-pocket costs with related lab tests and monitoring.[†]

Access
No charge for eligible patients experiencing initial insurance denial for up to 24 months.[‡]

Streamlined Enrollment Process
Get started with a **single enrollment form.**

Committed to AbbVie's exceptional access and patient support.
Enroll patients at **RINVOQHCP.COM/COMPLETE**

*Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing healthcare professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including further referrals.

†Eligibility: Available to patients with commercial insurance coverage for RINVOQ who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. **For full Terms and Conditions, visit RINVOQSavingsCard.com or call 1-800-2RINVOQ for additional information.** To learn about AbbVie's privacy practices and your privacy choices, visit **https://abbv.ie/corpprivacy**

‡Eligibility criteria: Available to patients aged 63 or younger with commercial insurance coverage. Patients must have a valid prescription for RINVOQ for an FDA-approved indication and a denial of insurance coverage based on a prior authorization request on file along with a confirmation of appeal. Continued eligibility for the program requires the submission of an appeal of the coverage denial every 180 days. Program provides for RINVOQ at no charge to patients for up to two years or until they receive insurance coverage approval, whichever occurs earlier, and is not contingent on purchase requirements of any kind. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage. No claims for payment may be submitted to any third party for product dispensed by program. Limitations may apply.

§RINVOQ is on a preferred tier or otherwise has preferred status on the plan's formulary.

‖Coverage requirements and benefit designs vary by payer and may change over time. Please consult with payers directly for the most current reimbursement policies.

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RINVOQ® upadacitinib

IMPORTANT SAFETY INFORMATION[1]

SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ until the infection is controlled.

Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treatment for latent TB infection prior to RINVOQ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MORTALITY

In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years old with at least one cardiovascular (CV) risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ.

In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk.

With RINVOQ, consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. Advise patients to limit sunlight exposure by wearing protective clothing and using sunscreen.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk. Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ, particularly in patients who are current or past smokers and patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death.

In a large, randomized, postmarketing study comparing another JAK inhibitor to TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of thrombosis was observed with the JAK inhibitor. Avoid RINVOQ in patients at risk. Patients with symptoms of thrombosis should discontinue RINVOQ and be promptly evaluated.

HYPERSENSITIVITY

RINVOQ is **contraindicated** in patients with known hypersensitivity to upadacitinib or any of its excipients. Serious hypersensitivity reactions, such as anaphylaxis and angioedema, were reported in patients receiving RINVOQ in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. Monitor RINVOQ-treated patients who may be at risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis and patients taking NSAIDs or corticosteroids). Promptly evaluate patients presenting with new onset abdominal pain for early identification of GI perforation.

LABORATORY ABNORMALITIES

Neutropenia

Treatment with RINVOQ was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm^3. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm^3 were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.

Anemia

Decreases in hemoglobin levels to <8 g/dL were reported in RINVOQ-treated patients. Treatment should not be initiated or should be interrupted in patients with hemoglobin levels <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Lipids

Treatment with RINVOQ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Manage patients according to clinical guidelines for the management of hyperlipidemia. Evaluate patients 12 weeks after initiation of treatment and thereafter according to the clinical guidelines for hyperlipidemia.

Liver enzyme elevations

Treatment with RINVOQ was associated with increased incidence of liver enzyme elevation compared to placebo. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are observed during routine patient management and drug-induced liver injury is suspected, RINVOQ should be interrupted until this diagnosis is excluded.

EMBRYO-FETAL TOXICITY

Based on findings in animal studies, RINVOQ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RINVOQ and for 4 weeks after the final dose. Verify pregnancy status of females of reproductive potential prior to starting treatment with RINVOQ.

VACCINATION

Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

MEDICATION RESIDUE IN STOOL

Reports of medication residue in stool or ostomy output have occurred in patients taking RINVOQ. Most reports described anatomic or functional GI conditions with shortened GI transit times. Instruct patients to contact their healthcare provider if medication residue is observed repeatedly. Monitor patients clinically and consider alternative treatment if there is an inadequate therapeutic response.

LACTATION

There are no data on the presence of RINVOQ in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in animals have shown the excretion of RINVOQ in milk. Advise patients that breastfeeding is not recommended during treatment with RINVOQ and for 6 days after the last dose.

HEPATIC IMPAIRMENT

RINVOQ is not recommended for use in patients with severe hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions in RINVOQ clinical trials were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, increased blood creatine phosphokinase, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, influenza-like illness, elevated liver enzymes, rash, and anemia.

Inform patients that retinal detachment has been reported in clinical trials with RINVOQ. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving RINVOQ.

Dosage Forms and Strengths: RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets..

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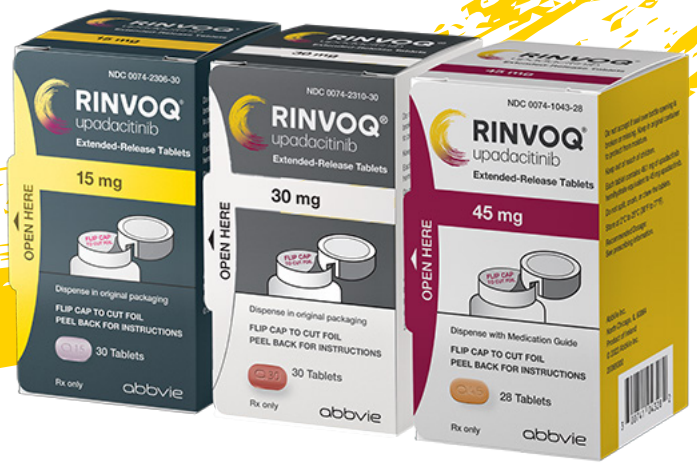
SCOPE OUT POWERFUL EFFICACY DATA



See the efficacy data at 1 year for RINVOQ
RINVOQHCP.COM/CD/EFFICACY

INDICATIONS[1]

RINVOQ is indicated for the treatment of adults with:

- **Moderately to severely active Crohn's disease** who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Moderately to severely active ulcerative colitis** who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biological therapies for Crohn's disease or ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

SAFETY CONSIDERATIONS[1]

Serious Infections: RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

Malignancies: Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

Thrombosis: Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information for RINVOQ, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 8.

Please visit rxabbvie.com/pdf/rinvoq_pi.pdf for full Prescribing Information.

References: 1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.; 2024. **2.** Roda G, Chien Ng S, Kotze PG, et al. Crohn's disease. *Nat Rev Dis Primers.* 2020;6(1):22. **3.** Data on file, AbbVie, Inc. April 2024.

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